DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
555 Winderly Place, Suite 200
Maitland, Florida 32751

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VIA FEDERAL EXPRESS

WARNING LETTER

FLA-00-35

March 6, 2000

FACILITY ID # 212423

Andrea Orane, Project Coordinator
Early Detection Project Mobile Van Number 2
1550 NW 10th Avenue, Room 100
University of Miami, School of Medicine
Miami, Florida 33136

Dear Ms. Orane:

Your facility was inspected on February 11, 2000 by a representative of the State of Florida, on contract to the Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with the Quality Standard for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

Level 1

Phantom QC records were missing for twelve weeks for the Mobile Van # 2.

Level 2

The following radiologic technologists, [redacted] and [redacted] did not meet the continuing education requirements of having completed a minimum of 15 CEUs in mammography in a 36-month period.

Level 3

The repeat analysis QC, the screen-film contact QC, and the darkroom fog QC were not adequate at the Mobile Van # 2, because the QC was not done at the required frequency.

The specific deficiencies noted above appeared on the List of Observations, which was issued to your facility on February 11, 2000. These deficiencies are symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the cause of these deficiencies that the inspection identifies and to promptly initiate permanent corrective actions.

If you fail to properly address these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- impose civil money penalties on a facility of up to $10,000 for each failure to substantially comply with, or each day of failure to comply with the Standards.
- suspend or revoke a facility's FDA certificate for failure to comply with the Standards.
- seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective action(s), therefore, you should consider the more stringent State requirements, if any.

Within 15 working days after receiving this letter, you should notify FDA in writing of each step your facility is taking to prevent the recurrence of similar violations.

If your facility is unable to complete the corrective actions within 15 working days, you should state the reason for the delay and the time within which the correction will be completed.

Your reply should be directed to Timothy J. Couzins, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

Sincerely,

Marie A Urban

Marie A. Urban
Acting Director
Florida District

cc: Florida Department of Health, Bureau of Radiation Control